I CLINICA ORTOPEDICA
DELL'UNIVERSITA' DI FIRENZE
Direttore: Prof. P. Aglietti

CENTRO TRAUMATOLOGICO
LARGO P. PALAGI, 1 - 50139 FIRENZE
(ITALY)
☎ 055 416901 - 4278341
Fax: 055 4224063
E-mail: ortosec@unifi.it

Office of Device Evaluation, Center for Device and
Radiological Health, Food and Drug Administration, 9200 Corporate
Boulevard,
Rockville, MD 20850 USA.

Topic: Mobile bearing knee designs reclassification

Dear Sirs:

I have an experience since 1993 with the M.B.K. (Meniscal Bearing Knee) of Zimmer, which I have used in over 300 cases. We have a randomised comparative clinical trial comparing M.B.K. to L.P.S. The results were the same with no advantages of the M.B.K. over the L.P.S. but also without disadvantages.
I am in support of the down-classing of mobile bearing knee systems from Class III to Class II.

Sincerely,

Professor Paolo Aglietti

P Aglietti

Dr. R.B. Bourne
Professor and Chairman
Division of Orthopaedic Surgery

The University of Western Ontario

April 22, 2003

Office of Device Evaluation
Center for Device & Radiological Health
Food & Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850
USA

To Whom it May Concern,

Re: Mobile Bearing Knee Systems

I would like to write in support of the initiative taken by the Orthopaedic Surgical Manufacturers Association (OSMA) in an effort to down-class mobile bearing knee systems from Class III to Class II. I have been a user of mobile bearing knee systems since 1978, starting with the Oxford meniscal knee replacement. Since that time, our unit has performed over 800 mobile bearing knee replacements using not only the Oxford knee systems, but also the LCS, SAL and SAL II implant designs. We have published on our experiences and have prospectively collected our data on all patients. It is our impression that mobile bearing knee replacements perform equally well to their fixed bearing counterparts and that these mobile bearing designs represent a further alternative to conventional knee arthroplasty with the prospect of enhanced conformity and reduce the surface and subsurface stress concentrations with the promise of increased device longevity.

Mobile bearing knee replacements offer similar patient improvement in terms of pain relief, improved health-related quality of life and range of motion. Specifically, our vast experience has not identified any increase of the need for revision surgery or other such complications.

I do hope that this down-classification is successful.

Sincerely,

R. B. Bourne, MD, FRCSC
Chair/Chief, Division of Orthopaedic Surgery
University of Western Ontario
RBB/lm

Office: (519) 663-3512 • Fax: (519) 663-3780 • E-mail: robert.bourne@lhsc.on.ca
London Health Sciences Centre, University Campus
339 Windermere Road, London, Ontario, Canada N6A 5A5

The University of Utah School of Medicine

Department of Orthopedics

30 North 1900 East, Rm. 3B165
Salt Lake City, Utah 84132-2302
(801) 581-7601
FAX# (801) 581-6178

April 18, 2003

Toni R. Kingsley, Ph.D.
Zimmer, Inc.
345 E. Main Street
Warsaw, IN 46581

Dear Dr. Kingsley,

I am writing this letter in support of the reclassification effort currently underway to downclassify mobile-bearing knee systems from Class III to Class II.

My personal experience includes working with and assisting in several surgeries with noted European surgeons, such as Prof. Neumann of Magdeburg, Germany, who is president of the German Orthopedics Society using the Natural-Knee® II Mobile Bearing Knee System. This is a central peg rotating platform design similar to the L.C.S. knee. The system is currently approved for sale in Europe and has been used in over 4,500 implant procedures to date. The European experience with mobile bearing knee surgery using this implant has led to very successful clinical outcomes.

One study in progress with this design is 998 primary Total Knee Replacements (TKR) has 672 fixed bearing and 326 mobile bearing knees. Of the 326 mobile bearing knees, 221 were cemented (68%), 27 were cementless (8%), and 78 were hybrid (24%). The average age was 63 with 128 male patients and 198 female patients. Of 162 patients with Hospital for Special Surgery (HSS) scores out to the 2-year mark: 122 had excellent results (85-100 points), 39 patients had good results (70-84 points), and only 1 patient had a poor result with 42 points. Thus a marked post-operative improvement was seen.

The data obtained from this study suggest that mobile bearing designs present several advantages over conventional knee arthroplasty. These include reduced shear forces and, therefore reduced stress on the polyethylene insert. The reduction of these forces should equate to reduced wear and longer life for the device.

Indications for use of this device are universal but most important for the younger patients where higher knee loads may be expected and where there is a need for greater mobility. The device has been and will be used both for posterior cruciate ligament (PCL) sparing as well as PCL substitution. A mobile bearing may significantly improve soft tissue balancing by providing for self-alignment, improve range of motion, and minimize the stress at the bone-baseplate interface. I believe mobile bearing knees will give us the best long-term durability of the polyethylene because of the high contact areas that can be designed into them.

It is my personal opinion that these devices offer a safe and effective alternative to conventional knee arthroplasty and their availability to the general public should be facilitated. Thank you for your consideration.

Sincerely,

Aaron A. Hofmann, M.D.
Professor of Orthopedics
The Louis S. Perry, M.D. and
Janet R. Perry Presidential
Endowed Chair in Orthopedics

AAH/agm

Athens Orthopedic Clinic P.A.
EST. 1966

125 King Avenue
Athens, Georgia
30606
(706) 549-1663
FAX (706) 546-8792

April 18, 2003

Office of Device Evaluation
Center for Device and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

To Whom It May Concern:

This letter is written in support of the FDA reclassification petition of mobile bearing knee arthroplasty systems from class III to class II. As you know, these devices are in exclusive use world-wide and offer significant potential advantages for reduction in wear. The devices also present short term advantages for selected cases in which proximal tibial deformities make conventional devices difficult to use, because of their relatively limited tibial rotational tolerances.

As the principal investigator of the Stryker Scorpio Mobile Bearing IDE, I have experience with 96 mobile bearing knees that are being carefully followed. The majority of these cases were osteoarthritic with a fairly active patient population (average age of 65). In this group the average Knee Society scores have improved from 31/43 to 89/81 at a year postop. The range of motion of these patients has improved from 102 degrees to 126 degrees over the same time period. There have been NO COMPONENT RELATED COMPLICATIONS in any of these patients.

In summary, these devices offer significant potential advantages over the long term and significant existing advantages in selected cases over the short term. Extensive experience outside the United States with these devices has been very gratifying for the patients who have received them and our short term experience here supports our expectation of similar long term results.

EST. 1966

I feel very strongly that these devices are safe and effective and offer significant advantages for selected patients. I hope that you will be able to down-classify these devices so that our patients here in the United States will be able to benefit from these technological advantages just as those in other countries have.

Sincerely,

Ormonde M. Mahoney, M.D

OMM/cj

Mayo Clinic
200 First Street SW
Rochester, Minnesota 55905
507-284-2511

Bernard F. Morrey, M.D.
Orthopedic Surgery

April 21, 2003

Office of Device Evaluation
Center for Device and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

To Whom It May Concern:

I am pleased to write this letter of support of the petition to down classify the Mobile Bearing Knee from a Class III to a Class II device. I have been very familiar with the design concept of this and other mobile bearing knee devices. The rationale for such a design is compelling. The concept of maintaining congruency and stability while decreasing stress on the articulation is a very attractive one as this should decrease wear and increase motion.

I was a co-principle investigator on a PMA study conducted by Zimmer on their particular knee, the MBK™. During this study I personally found the instrumentation to be quite easy to use and differs little from that of conventional joint replacement designs. The same is true for the implant itself. It is easy to insert and the added value of the tibial/tibial tray degrees of freedom adds no significant technical challenges that I could identify. None of the patients that we had placed in the study have been revised, and there were no intraoperative complications.

The postoperative course of these patients appears to be quite satisfactory. Only time will tell whether or not this does in fact decrease the wear associated with knee joint replacement. The arc of motion is certainly comparable to the traditional condylar type of knee replacement and, as mentioned above, there were no complications, so I would not anticipate any increased complication rate with this design.

Therefore based on my understanding of safety and efficacy considerations and my personal experience with this particular design and my awareness and experience with having published a book chapter on mobile bearing knees (Joint Reconstructive Surgery, Third Edition, B.F.Morrey, M.D. Editor, Churchill Livingstone 2003) I would endorse the favorable review of the petition to downclassify this device.

Should there be any questions concerning this recommendation, please do let me know.

Sincerely,

B. F. Morrey, M.D.

BFM:sjk

University of California
San Francisco
UCSF
Department of Orthopaedic Surgery

David S. Bradford, M.D.
Professor and Chairman
Spinal Disorders
Scoliosis/Spine Deformities
UCSF 415/476-2280

Sigurd H. Berven, M.D.
Spinal Disorders/Adult Reconstruction
UCSF 415/514-1519

W. Dilworth Cannon, Jr., M.D.
Sports Medicine/Arthroscopy
MT. ZION 415/353-7566

R. Richard Coughlin, M.D.
Trauma/Foot and Ankle Reconstruction
SFGH 415/206-8809

Eliana D. Delgado, M.D.
Pediatric Orthopaedics
UCSF 415/353-2212

Vedat Deviren, M.D.
Spinal Disorders
UCSF 415/353-2949

Mohammad Diab, M.D.
Pediatric Orthopaedics
UCSF 415/353-2808

Edward Diao, M.D.
Hand/Upper Extremity/ Reconstructive Microsurgery
UCSF 415/476-1167

Serena S. Hu, M.D.
Spinal Disorders
UCSF 415/476-7174

Harry E. Jergesen, M.D.
Adult Reconstruction
UCSF 415/514-1519

Hubert Kim, M.D.
Adult Reconstruction
UCSF 415/476-1166

Alicia A. Knee, D.P.M.
Podiatric Medicine and Surgery
MT. ZION 415/353-7200

Lisa L. Lattanza, M.D.
Hand/Upper Extremity/ Microvascular Surgery/ Elbow Reconstruction
UCSF 415/476-1167

Sandra L. Martin, D.P.M.
Podiatric Medicine and Surgery
SFGH 415/206-8812

Theodore Miclau, M.D.
Trauma
SFGH 415/206-8812

Richard J. O'Donnell, M.D.
Orthopaedic Oncology
MT. ZION 415/353-7962

Guy D. Paiement, M.D.
Trauma/Adult Reconstruction
SFGH 415/206-8812

Michael D. Ries, M.D.
Adult Reconstruction/Arthroplasty
UCSF 415/502-2235

Marc Safran, M.D.
Sports Medicine
MT. ZION 415/353-7566

Bobby K-B Tay, M.D.
Spinal Disorders
SFGH 415/206-8812

ORTHOPAEDIC RESEARCH LABORATORIES

Jill A. Helms, D.D.S., Ph.D.
Molecular Biology
UCSF 415/502-6523

Jeffrey C. Lotz, Ph.D.
Bioengineering
UCSF 415/476-7881

Christian Puttlitz, Ph.D.
Biomechanics
UCSF 415/502-4947

http://www.ucsf.edu/orthopaedics

April 17, 2003

Office of Device Evaluation
Center for Device and Radiologic Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Dear FDA Panel Members:

I am writing this letter in support of a current proposal for an FDA reclassification petition of mobile-bearing knee systems Class III to Class II. I am a practicing orthopaedic surgeon at an academic medical center, and specialize in total hip and knee arthroplasty. I have used a number of different knee implant systems. I am currently participating in a randomized prospective study comparing the Genesis II mobile bearing knee system with a similar fixed bearing.

Mobile-bearing knees have been used clinically for many years with excellent long-term results and close to 100 percent 10 year survivorship. The laboratory studies, which demonstrate low contact stresses and low bone-implant-interface stresses, are consistent with the clinical success of mobile bearing knee implants. I believe that these devices should be made available to the orthopaedic community in the United States. The down classification would permit access to these devices to improve the quality of care for arthritis patients, potentially improve the longevity of knee replacements, and stimulate further design improvements. I understand the reasons for FDA restrictions to introduction of new devices but feel that mobile bearings are a class of implant systems with proven safety and efficacy and their general availability to the orthopedic community in United States is long overdue.

Sincerely,

Michael Ries, M.D.
Vice Chair, Professor in Residence

UCSF MEDICAL CENTER
500 Parnassus Avenue (MU-320W)
San Francisco, CA 94143-0728
tel: 415/476-1166
fax: 415/476-1304

SAN FRANCISCO GENERAL HOSPITAL
1001 Potrero Avenue, (3A36)
San Francisco, CA 94110-0842
tel: 415/206-8812
fax: 415/647-3733

MT. ZION MEDICAL CENTER
1701 Divisadero Street
San Francisco, CA 94115
tel: 415/353-7200
fax: 415/353-7299

ISK
Insall Scott Kelly
Institute for Orthopaedics
and Sports Medicine

GILES R. SCUDERI, M.D., F.A.C.S.
Section Chief
Adult Knee Reconstruction
Assistant Clinical Professor
of Orthopaedic Surgery
Albert Einstein College of Medicine

SURGERY OF THE KNEE
SPORTS MEDICINE
TOTAL JOINT REPLACEMENT

April 17, 2003

Office of Device Evaluation
Center for Device and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Dear Committee Members:

At this time you are reviewing a FDA reclassification petition for down-classing mobile bearing knee systems from Class III to Class II and I would like to share with you my experience in support of this reclassification. Over the years, I have had the opportunity to clinically evaluate and implant numerous prosthetic knee designs. I have also had the opportunity to revise failed implants and analyse the mechanisms of failure. Currently, one of the biggest issues in implant failure is polyethylene wear and osteolysis. While this may be related to the material properties of polyethylene, it is also influenced by implant design.

It has been well documented that unconstrained fixed bearing prosthetic knee designs produce high contact stresses on the tibial polyethylene with resultant polyethylene damage, particulate debris, and subsequent osteolysis. A fully conforming articulation reduces the contact stress on the polyethylene, but creates a kinematic conflict by restricting the freedom of motion. A mobile bearing design provides a solution to this problem. The dual articulation of a mobile bearing design offers articular conformity along with greater freedom of motion.

Backsurface wear has also been implicated as a source of polyethylene debris leading to osteolysis in modular fixed bearing knee designs. As a solution to this problem, a mobile bearing knee can direct the degree of motion between the tibial base plate and the tibial polyethylene.

Rotational stress on the polyethylene post has been implicated with tibial post wear in fixed bearing posterior stabilized knee implants. A mobile bearing articulation will reduce the rotational stress on the tibial post. As the knee flexes, the tibial component follows the femoral component and the rotating platform in the mobile bearing design will move, reproducing the normal screw home mechanism of the knee thereby reducing the polyethylene stress.

170 East End Avenue at 87th Street, New York, New York 10128
Voice 212 870 9760 Fax 212 734 2387 gscuderi@bethisraelny.org
BETH ISRAEL MEDICAL CENTER HERBERT AND NELL SINGER DIVISION A MEMBER OF CONTINUUM HEALTH PARTNERS, INC.

My own experience centers on the Zimmer MBK Prosthesis, the Zimmer Rotating Hinge and the Zimmer Legacy Posterior Stabilized Flex Mobile Prosthesis. As part of the design team with the LPS Flex mobile prosthesis, a mobile bearing rotating platform for the tibial component was selected for all the reasons described above. In addition, tibial rotation that occurs in deep flexion can be reproduced with the mobile bearing rotating platform, thereby reducing the stress on the articular surface. Greater predictable femoral rollback has also been observed with the mobile articulation. I have been implanting this implant as part of current FDA approved IDE and feel that the LPS Flex Mobile Prosthesis has been performing well, with outcomes similar to the fixed bearing design.

Since the introduction of the Oxford Knee in 1977 and the LCS Total Knee System, numerous mobile bearing knee designs have been developed and are in global use. The use of the LCS Prosthesis and the PFC Sigma Rotating Platform (Depuy) in the United States further supports the reclassification of mobile bearing knee designs. The reported long- term experience has been salutatory. This is due, not only to the excellent clinical outcomes but patient satisfaction. Refinements in surgical technique and implant technology will increase the longevity of the implants. It is not only the improvements in materials, but improvements in prosthetic design, with implants like mobile bearing knee prostheses, that will lead to future clinical success and implant longevity. Mobile bearing knee designs represent an alternative to conventional fixed bearing designs. Hopefully the committee will look favorably on the reclassification so that the orthopedic community can offer the modern total knee implants to patients without restrictions.

Sincerely,

Giles R. Scuderi, M.D.

Alan H. Wilde, M.D.
Bernard N. Stulberg, M.D.

LETTER IN SUPPORT OF DOWNCLASSIFICATION PETITION ON MOBILE BEARING KNEE IMPLANTS:

Office of Device Evaluation
Center for Device and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

As academic orthopaedic surgeons interested in the growth and evolution of joint replacement procedures in the United States, we are pleased to provide this letter in support of the Orthopaedic Surgical Manufacturers Association (OSMA) petition for reclassification of MBK devices from Class III to Class II (with special controls) devices. There are many reasons why now appears to be an appropriate time to approve such a petition, and many of these reasons are enumerated in the accompanying documents. We would like to highlight several points that might not be readily apparent from the manufacturer's viewpoint, but are compelling from a clinician's perspective.

Each of us has had extensive experience with the design and development of implants and instruments for total knee replacement (TKA) systems over the past 2 decades. We also have participated in careful scientific and clinical evaluation of primary and revision TKA devices. In particular, we are each familiar with the influence of device design, materials and implantation techniques that lead to failure of TKA as an operation as well as failure of the device. In our personal practices we have only limited experience with mobile bearing knee devices. We each believe, however, that it is time for reclassification of these devices to allow the availability of these devices to surgeons in the US.

There are 4 points we wish to make in this letter. They are the following:

1) Our specialty has a clear understanding of the mechanisms of failure of TKA devices and is consistently looking for means to address causes of failure through device design and manufacture, improved implantation techniques and instruments, and patient education and rehabilitation;
2) There appear to be clear trends toward TKA implantation in younger and more active patient populations – populations that will require devices that potentially decrease wear rates while accommodating ever increasing demands to improve range of motion.
3) There is a large national and international experience with MBK devices with substantial literature describing this experience. While this experience has been heavily weighted toward a single system of MBK devices, sufficient experience has been gained outside of the US that defines the parameters of

Main Office: Lutheran Hospital 1730 W. 25th Street Cleveland, Ohio 44113-3108
Appointments: (216)363-3300 (800)837-3315 Fax (216)736-7969

Other Offices: Brooklyn Beachwood

design and implementation that make these MBK approaches equally safe to those approaches with fixed bearing devices;

4) The accompanying document represents genuine corporate collaboration within our industry to meet a need repeatedly articulated by the American Orthopaedic surgical population for access to particular devices that allow them to provide predictability and durability for their patients.

We will expand briefly on these 4 points:

1) TKA failure mechanisms: TKA has proven to be an enormously successful and predictable operation to address end stage arthritis of the knee. Its success (greater than 90% survivorship for 15 or more years) has resulted from concepts of knee arthroplasty that have been refined over 30 years. Failure mechanisms are often multifactorial, and can generally be thought of as *device related, technique related, or patient-factor related.* Currently, most investigators believe it the mechanisms of wear, instability and/or loosening that most commonly result in the need for revision. If these happen early after implantation (< 2years) they are likely to be related to technical aspects of implantation. If they occur late (greater than 10 years) the sources of failure are more likely to be features of implant design, material and/or wear. Significant improvement has occurred in our understanding of TKA implantation techniques and TKA in-vivo kinematics to help clinicians address the factors related to early and late failure. The design features of mobile bearings for TKA articulations could prove a significant advance in addressing the late failures due to wear, and could increase the zone of safety for TKA devices. This would increase the clinicians' confidence in facing situations where device performance of 20 or more years might be needed.

2) Options for the young, active patients: The experience with the presently available MBK to date (the LCS, Depuy) has suggested remarkably low wear rates for as long as 25 years following implantation. A recently reported worldwide multicenter study of this device suggests that this performance is predictable over a broad range of centers and surgical experience. Two important features of this study suggest that providing for availability of mobile bearing alternatives within knee systems can be accommodated with compromising safety or efficacy of devices: a) it does not appear that the ROM of these devices is substantially different than those of fixed bearing devices – suggesting that ROM is related to other features of design and implantation; and b) with proper training, the devices can be placed predictably and result in low rates of implant failure. Most surgeons performing TKA have become familiar with a particular philosophy of TKA. They approach TKA with these devices and systems in a predictable manner. Reclassification of MBK devices would allow surgeons to use bearing surfaces with potentially improved wear characteristics without sacrificing the predictability that they have achieved using specific device and implantation

systems. At present, should they wish to use a MBK for a particular patient, they might need to use a device where their familiarity is low.

3) National and International Experience: The reclassification petition submitted assembles an expanding experience with MBK with differing design and implantation philosophies. Many of these devices have evolved to a level of predictability that makes them equal to fixed bearing alternatives. The petition addresses those features know to allow safe usage of these devices to take advantage of the potential benefit of decreased wear.

4) Corporate Collaboration: In an increasingly competitive but expanding market, it is reassuring to clinicians that our industry has listened to its constituent surgeons' request that they work together. There is growing consensus among the clinical world of orthopaedics that MBK devices will have a specific role in the armamentarium of the American Orthopaedist performing TKA. We believe this petition represents an excellent example of an industry responding to its providers request to provide them with devices that can address specific demands of the patient population they serve. We believe this effort has been responsibly conducted, and with a high degree of scientific rigor.

At present, only 1 manufacturer in the US has the ability to integrate a MBK articulating surface option into a system of Knee devices using a single philosophy of knee implantation. There is sufficient information in the currently available literature, as well as an expanding body of knowledge being collected, that suggests that this option of MB articulation will be an important optional tool in the surgeon's armamentarium. We strongly support this reclassification petition as an important step in assuring this availability in the near future.

Bernard N. Stulberg, MD

Director of the Cleveland Center for Joint Reconstruction

Missouri Bone & Joint Center

Leo A. Whiteside, M.D.
Arthritis & Adult Reconstructive Orthopaedic Surgery

April 17, 2003

Toni R. Kingsley, Ph.D.
Zimmer, Inc.
345 East Main Street
Warsaw, IN 46581

Dear Dr. Kingsley:

I am writing to express my support for down-classifying mobile bearing knees. I am currently involved in a FDA study on the safety and efficacy of a mobile bearing knee with Smith & Nephew, and after having used this knee, I am convinced that it is the appropriate implant for many of my patients. Mobile bearing knees have been available in the US for about 20 years, and at least two brands are currently available. They have also had extensive use in Canada, Europe and Asia and have been an effective solution to knee arthritis. The manufacturing and engineering issues have been thoroughly worked out, and it is time to release this to the general public. Allowing all manufacturer's to produce mobile bearing knees and have them approved through the 510 (k) process would improve the availability of this technology to all practitioners and patients, and would also result in much more rapid progression of innovation and thereby, evolution of these products.

Thank you for allowing me the chance to express my opinion.

Sincerely,

Leo A. Whiteside, M. D.
LSW/bmm

10 Barnes West Drive, Suite 100 St. Louis, Missouri 63141 Office (314) 205-2223 Exchange (314) 995-1353 Fax (314) 205-2324